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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,284	03/01/2005	Manfred Auer	DC/4-32653A	7466
1095	7590	01/27/2006	EXAMINER	
NOVARTIS CORPORATE INTELLECTUAL PROPERTY ONE HEALTH PLAZA 104/3 EAST HANOVER, NJ 07936-1080			MARTIN, PAUL C	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/526,284	Applicant(s) AUER ET AL.	
	Examiner Paul C. Martin	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>03/01/05, 10/04/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-8 are pending in this application and were examined on their merits.

Specification

The use of the trademark Axiovert™ has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

Claims 1-3 and 5 are objected to because of the following informalities: The term “biological active” should read as “biologically active”. Appropriate correction is required.

Claim 5 is objected to because of the following informalities: The first use of T-cells in line one is missing an “s”. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, line (e) of Claim 1 describes the choosing of an agent from the candidate compound but the claim does not specify or indicate how to separate the actions of the agent from the actions of the compound, or if indeed, the agent and the compound may not be one and the same.

The instant specification describes a candidate compound as a compound which may modulate T-cells and which may be oligopeptides, polypeptides, proteins, antibodies, mimetics, or small molecules. An agent is defined as a *candidate compound* which modulates the amount of cytokine produced by T-cells and which may be oligopeptides, polypeptides, proteins, antibodies, mimetics, or small molecules (Pg 4, Lines 21-31).

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Claims 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6-8 provides for the use of transfected primary T-cells in a cellular screening assay, for biological profiling of compounds, and in a high throughput screening assay but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Jimenez *et al.* (2001).

Jimenez *et al.* teaches a cellular assay for identifying an agent that modulates T-cells comprising the steps of:

a) providing primary T-cells transfected with a nucleic acid containing plasmid (P. 754, Column 1, Lines 36-41 and Column 2, Lines 1-15),

b) stimulating the transfected T-cells in the presence and absence of a compound for a sufficient period of time (Pg. 754, Column 2, Lines 46-53),

c) detecting the amount of cytokine produced by the T-cells, the amount of a reporter molecule and the proliferation of the T-cells (Pg. 754, Column 2, Lines 54-60 and Figs 1A-B, and Pg. 756, Column 1, Lines 30-37 and Fig. 3),

d) determining if there is a difference in the amount of cytokine produced, the amount of reporter molecule and in the amount of proliferation in the absence and in the presence of a compound (Pg. 754, Column 2, Lines 54-60 and Figs 1A-B, and Pg. 756, Column 1, Lines 30-37 and Fig. 3),

e) choosing an agent from said candidate compound as determined in step (d).

For purposes of examination, it is deemed by the examiner based on the instant specification that the candidate compound and agent are the same entity and therefore there is no need to choose an agent from the candidate compound.

Jimenez *et al.* teaches a method wherein the biologically active molecule is a DNA (Pg. 754, Column 2, Lines 1-15).

Jimenez *et al.* teaches a method wherein the transfection step is accomplished by use of a non-viral transfection method (Pg. 754, Column 2, Lines 16-29).

Jimenez *et al.* teaches the use of transfected primary T-cells in a cellular screening assay (Pg. 754, Column 2, Lines 54-60 and Figs 1A-B, and Pg. 756, Column 1, Lines 30-37 and Fig. 3).

Jimenez *et al.* teaches the use of transfected primary T-cells for biological profiling of compounds (Pg. 754, Column 2, Lines 54-60 and Figs 1A-B, and Pg. 756, Column 1, Lines 30-37 and Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jimenez *et al.* (2001) in view of Tinsley *et al.* (1998).

The teachings of Jimenez *et al.* were discussed *supra*.

Jimenez does not teach a method wherein the biologically active molecule is a protein.

Jimenez does not teach the use of a kit for identifying an agent that modulates T-cells.

Jimenez does not teach the use of transfected primary T-cells in a high throughput screening assay.

Tinsley *et al.* teaches the use of a protein as a transfected biologically active molecule (Pg. H1873, Column 2, Lines 38-42).

It would have been obvious to one of ordinary skill at the time of invention to combine the method of Jimenez *et al.* with the transfection of a protein as practiced by Tinsley *et al.* because of the advantages described by Tinsley *et al.* The ordinary artisan would have been motivated to do so because of the advantages described such as the low efficiency of transfection using DNA and the short period of time required for successful transfection of a protein vs. DNA. The direct transfection of protein eliminates the need for construction of plasmids, screening transfected colonies, large scale plasmid preparation and transformation of the desired cells, a process that can take multiple days. The ordinary artisan would have had a reasonable expectation of success based on the success of the methods of Jimenez and Tinsley individually.

It would have been obvious to one of ordinary skill in the art at the time of invention to adapt the method of Jimenez *et al.* for the identification of an agent that modulates T-cells, as the basis for the composition of a kit to perform that method because it was well known in the art that a kit is a useful and efficient means of compiling all the necessary components and instructions needed to perform a task in one location.

The ordinary artisan would have been motivated to compile such a kit so as to streamline the performance and increase time-efficiency in identifying agents that can modulate T-cells. The ordinary artisan would have had a reasonable expectation of success based on the components and protocol for the experimental procedure already having been described and utilized in the method taught by Jimenez *et al.*

It would have been obvious to one of ordinary skill in the art at the time of invention to use the transfected primary T-cells of Jimenez *et al.* in a high throughput screening assay because this would enable the screening of a large number of candidate compounds in a short period of time. The ordinary artisan would have been motivated to increase the number of screened compounds because in this would more quickly identify candidate compounds with the desired action of modulating T-cells instead of the method of Jimenez *et al.* which only provides screening of a few compounds per experiment. The ordinary artisan would have had a reasonable expectation of success based on the wide availability of methods and protocols known in the art for adapting methods to high throughput capabilities.

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From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole is *prima facie* obvious to one with ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul C. Martin whose telephone number is 571-272-3348. The examiner can normally be reached on M-F 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul Martin
Examiner
Art Unit 1655

01/10/06

PATRICIA LEITH
PRIMARY EXAMINER

